



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/674,975 | 11/07/2000 | David B. Agus | MSKP039 | 8051 |

21121 7590 01/13/2003
OPPEDAHL AND LARSON LLP
P O BOX 5068
DILLON, CO 80435-5068

EXAMINER

UNGAR, SUSAN NMN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 01/13/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/674,975

Applicant(s)
Agus et al

Examiner
Ungar

Art Unit
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 18, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1642

1. Claims 1-20 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13:

Group I, claims 1-8 drawn to a method for active vaccination against autologous cells expressing transmembrane proteins.

Group II, claims 9-11 are drawn to a method for active vaccination against B cells expressing CD20.

Group III, claim 12 is drawn to a method of treating B cell non-Hodgkin's lymphoma.

Group IV, claims 13-20 are drawn to a vaccine composition comprising at least an immunogenic portion of the extracellular domain of the transmembrane protein.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is

Art Unit: 1642

fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as Groups I-IV do not relate to a single inventive concept because they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IV appears to be that they all relate to a method of active vaccination. However, US Patent No. 5,550,214 (IDS item) teaches a method for active peptide vaccine wherein the immunogen is HER2/neu wherein a pharmaceutically-acceptable carrier is included (col 17, lines 60-65), wherein the carrier is a protein such as BCG, wherein an adjuvant is included and is selected from a group including Freund's complete or incomplete adjuvant (col 19, lines 51-65). It would be an inherent property of the method to vaccinate against B cells.

Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCTRule 13.2, as it does not define a contribution over the prior art.

In view of the above, Group I is considered the main invention. After that, all other products and methods have been broken out as separate groups (see 37 CAR 1.475(d)).

4. Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

Art Unit: 1642

5. Groups I, IV contains claims directed to more than one species of the generic invention.

Claims 1, 13 are generic to a plurality of disclosed species comprising transmembrane proteins with different structures and functions wherein the proteins are (a) CD20, Her2-neu, VEGF receptor, epidermal growth factor receptor, CD19 molecule, interleukin-2-receptor, interleukin-4-receptor and the P-glycoprotein of claims 2 and 6, 14 and 18. Claims reciting the individual transmembrane proteins will be examined as they are drawn to the elected species.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

Art Unit: 1642

made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, Ph.D. whose telephone number is (703) 308-305-2181.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Serial No: 09/674,975

Page 6

Art Unit: 1642

A handwritten signature in black ink, appearing to read "Susan Ungar". The signature is fluid and cursive, with a large initial "S" and a stylized "U".

Susan Ungar

Primary Patent Examiner

January 10, 2003